

PSJ4 SOL Opp App A Exh 18

From: Terrance Woodworth <twoodworth@thedcag.com>
To: Strehlke, Brian [GPSUS]; Dempsey, Michele [GPSUS]
Sent: 2/6/2018 11:13:06 PM
Subject: [EXTERNAL] RE: Question
Attachments: Draft SOM Report for JOM.pdf

Hi Brian,

Okay; sentence has been deleted!

Yes, I am in agreement with all your take-away comments! And, I would add that we felt the current algorithm was one dimensional and thus had some drawbacks that could be addressed by enhancing the algorithm.

It was a very productive time together in December, and quite a pleasure to see you and Michele after so long!

All the best,

Terry

On February 6, 2018 at 10:57 AM "Strehlke, Brian [GPSUS]" <BSTREHLK@its.jnj.com> wrote:

Hi Terry,

That sounds fine to me.

From our time spent together in December, I took away that:

1. Our system has been working well.
2. There is an identified weakness with Schedule III orders that come in late in the day requiring manual processing to verify their nonsuspicious nature.
3. You made recommendations necessary to enhance our process to meet changing regulatory expectations.
4. There have been no orders identified as suspicious and thus there have been none reported.

Are you in agreement with the above?

Best Regards,

Brian

From: Terrance Woodworth [mailto:twoodworth@thedcag.com]
Sent: Tuesday, February 06, 2018 5:25 AM
To: Dempsey, Michele [GPSUS] <MDempse3@its.jnj.com>
Cc: Strehlke, Brian [GPSUS] <BSTREHLK@its.jnj.com>
Subject: [EXTERNAL] RE: Question

Hi Michele and Brian,

I hope you both are doing well!

I am happy to just delete this sentence altogether. It really doesn't fit well with the recommendation being made. What do you think?

And, if this is okay, do you want me to send you a new draft with the sentence omitted?

Thank you Michele and Brian!!

Terry

On February 5, 2018 at 3:26 PM "Dempsey, Michele [GPSUS]" wrote:

Hello Terry!

During the review last week – Brian pointed out one statement that I think needs to be clarified. The below statement in red can be misleading. Perhaps you could consider rewording? Something like “Due to the current algorithm and order investigation process, there has not been any deemed suspicious that would require reporting”?

Start updating your SOM SOPs with additional elements and enhancements, including new data sources that are being used and additional information that will be evaluated. Expand the procedures for documenting and reporting a suspicious order to DEA, including to whom the report should be furnished, what information should be included in the report, which J&J employee should make the report and in what form or forms (verbal initially, followed with written report). It appears that the JOM SOM has not reported an order for controlled substances as suspicious during its time in operation

Regards,
Michele